UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Informed Consent Action Network,

Plaintiff,

–v–

United States Food and Drug Administration,

Defendant.

20-cv-689 (AJN)

MEMORANDUM OPINION & ORDER

ALISON J. NATHAN, District Judge:

This action concerns Plaintiff Informed Consent Action Network's ("ICAN") request under the Freedom of Information Act for records reviewed by the Food and Drug Administration in licensing a particular vaccine for children. Before the Court are the parties' cross-motions for summary judgment. For the following reasons, the Court GRANTS the FDA's motion for summary judgment and DENIES ICAN's motion.

I. Background

"In ruling on a motion for summary judgment, a court must resolve all ambiguities and draw all factual inferences in favor of the nonmoving party." *McClellan v. Smith*, 439 F.3d 137, 144 (2d Cir. 2006). The operative facts of this case are effectively undisputed.[1]

The FDA is tasked with testing and licensing vaccines for children. *See* 42 U.S.C. § 300aa-27(a); 21 C.F.R. §§ 601.2, 601.5(b)(1)(vi). In 1989, the FDA licensed for use in children Engerix-B, which prevents Hepatitis B infection. Burk Decl. ¶¶ 10, 13; Am. Compl.

[1] The Court refers to the amended complaint, Dkt. No. 9, the two sworn affidavits submitted by the FDA, Burk Decl., Dkt. No. 16; Burk Suppl. Decl., Dkt. No. 20, and the exhibits attached to ICAN's briefing, Dkt. Nos. 18, 26.

¶ 16. The Centers for Disease Control recommend that infants receive the vaccine. Am. Compl. ¶ 15.

ICAN is "a non-profit organization that advocates for informed consent with regard to all medical interventions." *Id.* ¶¶ 3, 5. On June 21, 2019, ICAN submitted a FOIA request to the FDA for:

> A copy of the report for each clinical trial relied upon by the FDA to approve Engerix-B for babies and children in 1989 that had a safety review period longer than seven days following administration of this vaccine.

Burk Decl., Ex. A ("FOIA Request") at 1; Am. Compl. ¶ 18.

The FDA responded to the request on July 9, 2019, stating in part:

> The subject request[ ] do[es] not reasonably describe the records that you are seeking in a way that the records can be identified and located. Per our regulation in Title 21 CFR 20.40(b) "A request should include all pertinent details that will help identify the records sought." Although you have identified the brand name of the vaccine of interest, as well as a date range, you have not provided information related to the clinical trial(s) for which you are seeking reports in a way that allows us to search our record systems without reading all the records in the application file and trying to identify which clinical studies may have had "a safety review period longer than 7 days."

Burk Decl., Ex. B-1; Am. Compl. ¶ 19.

ICAN on July 9, 2019, clarified that it sought "pre-licensure clinical trials," but otherwise maintained its language that it sought only trials "that had a safety review period longer than seven days." Burk Decl., Ex. B-2; Am. Compl. ¶ 20. The FDA sent a response on July 26, 2019, in which it stated that it interpreted ICAN to be asking for "the clinical trial reports submitted by the sponsor for the original [Biologics License Application] for Engerix B." Burk Decl., Ex. B-3 at 2. The FDA "also explained that [it is] unable to search or locate records by information that may be included in the records, i.e. '*that had a safety review period longer than seven days*.'" *Id.* It asked if ICAN would "agree to amend the wording of this request to '*The clinical trial reports submitted by the sponsor for the original [Biologics License Application]*

for Engerix B.'" *Id.* In other words, the FDA proposed "to provide the full set of the pre-licensure clinical trial reports." FDA Br. at 4, Dkt. No. 15. ICAN responded that it "d[id] not agree to modify the language of the request[ ]." Burk Decl., Ex. B-4.

On August 13, 2019, the FDA informed ICAN that because it is "unable to search or locate records in the way in which [ICAN] describe[d] the records," the FDA closed the request. Burk Decl., Ex. C at 1. ICAN on January 24, 2020, filed this action. Dkt. No. 1. On July 10, 2020, the FDA filed a motion for summary judgment. Dkt. No. 14. ICAN filed a cross-motion for summary judgment on August 14, 2020. Dkt. No. 17; ICAN Br., Dkt. No. 18. The motions are fully briefed. FDA Reply Br., Dkt. No. 19; ICAN Reply Br., Dkt. No. 26.[2]

II. Legal Standard

The Freedom of Information Act "was enacted to promote honest and open government and to assure the existence of an informed citizenry 'to hold the governors accountable to the governed.'" *Grand Cent. P'ship, Inc. v. Cuomo*, 166 F.3d 473, 478 (2d Cir. 1999) (quoting *Ethyl Corp. v. EPA*, 25 F.3d 1241, 1245 (4th Cir. 1994)). It entitles members of the public "to have access to any record maintained by a federal agency, unless that record is exempt from disclosure." *A. Michael's Piano, Inc. v. FTC*, 18 F.3d 138, 143 (2d Cir. 1994).

"Summary judgment is the procedural vehicle by which most FOIA actions are resolved." *Seife v. U.S. Dep't of State*, 298 F. Supp. 3d 592, 604 (S.D.N.Y. 2018) (citation omitted). As a general matter, a court may not grant summary judgment unless the parties' submissions, taken together, show that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In a FOIA case,

[2] ICAN also requested discovery into the FDA's use of the phrase "safety review period" and into emails and documents concerning the present FOIA request. ICAN Reply Br. at 23. The Court resolved that request by separate order. Dkt. Nos. 25, 30.

"[a]ffidavits or declarations supplying facts indicating that the agency has conducted a thorough search" are "'accorded a presumption of good faith'" by courts. *Carney v. U.S. Dep't of Just.*, 19 F.3d 807, 812 (2d Cir. 1994) (quoting *SafeCard Servs., Inc. v. SEC*, 926 F.2d 1197, 1200 (D.C. Cir. 1991)). Where agency submissions are "adequate on their face," a district court may award summary judgment in the agency's favor on the basis of its affidavits alone. *Id.* If the agency defendant fails to meet its burden of showing that the requested information may be withheld, the court may grant summary judgment to the party requesting information. *See NRDC v. U.S. Dep't of Interior*, 36 F. Supp. 3d 384, 398, 406 (S.D.N.Y. 2014); *Schladetsch v. Dep't of Hous. & Urb. Dev.*, No. 99-0175, 2000 WL 33372125, at *3 (D.D.C. 2000) ("[I]f the [agency] affidavits do not meet this standard, not only is summary judgment not appropriate in favor of the government, but such remedy may well be called for, as a matter of law, for those persons seeking the information." (quotation omitted)).

A threshold requirement under FOIA is that the request must "reasonably describe[ ]" the records sought. 5 U.S.C. § 552(a)(3)(A). A request "reasonably describes" the records "if a professional employee of the agency familiar with the subject matter can locate the records with a reasonable amount of effort." *Seife*, 298 F. Supp. 3d at 611 (quoting *Freedom Watch, Inc. v. Cent. Intel. Agency*, 895 F. Supp. 2d 221, 228 (D.D.C. 2012)); *see also Yagman v. Pompeo*, 868 F.3d 1075, 1081 (9th Cir. 2017) (finding a description was not reasonable if the agency "could not know what records would be responsive"). Given the variety of subjects that FOIA requests may cover, this is necessarily a "highly context-specific inquiry." *Nat'l Sec. Couns. v. C.I.A.*, 898 F. Supp. 2d 233, 278 (D.D.C. 2012), *aff'd sub nom.*, 969 F.3d 406 (D.C. Cir. 2020). The purpose of the requirement is to enable the agency to locate the records in question; it is "not to be used as a method of withholding records." *Pub. Emps. for Env't Resp. v. U.S. Env't Prot.*

Agency, 314 F. Supp. 3d 68, 74 (D.D.C. 2018) (quoting *Bristol-Myers Co. v. F.T.C.*, 424 F.2d 935, 938 (D.C. Cir. 1970)).

If this requirement is not satisfied, the agency "is under no obligation to release records that have not been reasonably described." *Dale v. I.R.S.*, 238 F. Supp. 2d 99, 104 (D.D.C. 2002).[3] But when the FDA receives an ambiguous request, it has an obligation to "notify the person making the request and indicate the additional information needed to identify the records requested," and then to make "[e]very reasonable effort . . . to assist in the identification and location of the records sought." 21 C.F.R. § 20.40(b).

III. Discussion

The FDA argues that summary judgment is justified because ICAN's request—namely, for only those trials "that had a safety review period longer than seven days following administration of this vaccine"—did not "reasonably describe" the records sought. ICAN responds that its request was sufficiently specific and requests summary judgment in its favor. Notably, the FDA has identified the full universe of potentially responsive records—approximately 3,000 pages of clinical trial reports stored in hardcopy in the FDA's Maryland office. Burk Decl. ¶¶ 12–13. The dispute is about whether ICAN has reasonably described which of those 3,000 pages it seeks so that the FDA may identify, review, and produce them.

The Court concludes that the request did not reasonably describe the records sought and therefore agrees with the FDA. At the outset, the Court agrees that the phrase "safety review period" has a seemingly plain meaning: It "refers to the period of time safety was reviewed after

[3] Some courts explain the failure to reasonably describe records as a failure to satisfy FOIA's administrative-exhaustion requirement, which may implicate the court's jurisdiction. *E.g.*, *Manfredonia v. S.E.C.*, No. 08-CV-1678 (SLT), 2009 WL 4505510, at *5 (E.D.N.Y. Dec. 3, 2009); *Freedom Watch, Inc. v. Fed. Bureau of Investigation*, No. CV 18-1912 (JEB), 2019 WL 108879, at *2 (D.D.C. Jan. 4, 2019). The distinction makes no difference here.

administering the vaccine." ICAN Br. at 15. And here ICAN specified that the period of time is seven days measured from the date the vaccine was administered. *Id.* at 16. ICAN also correctly observes that the term has appeared in "a few FDA documents regarding drug trials." FDA Reply Br. at 4 (citing ICAN Br. at 15–16 & nn.38–40); *see, e.g.*, Teresa Buracchio, *Cross-Discipline Team Leader Review* (Sept. 8, 2017), https://www.fda.gov/media/109082/download. And it appears in several academic articles, though only infrequently and in isolation. *E.g.*, B. Brian Smith et al., *Safety Monitoring of Drugs Receiving Pediatric Marketing Exclusivity*, Pediatrics, Sept. 2008, at e623–e633 (using the phrase once).

But ICAN's request contains latent ambiguities that prevent an FDA employee, even one "familiar with the subject matter," from determining which of the 3,000 identified pages ICAN would consider responsive and which not. *Seife*, 298 F. Supp. 3d at 611. To start, Engerix-B is delivered not as one shot but rather as several doses spread out over months. Burk Decl. ¶ 20; Am. Compl. ¶ 15 (describing Engerix-B as a "three-dose Hepatitis B vaccine"). The FDA represents that the trials submitted in support of Engerix-B in 1989 reflect that multiple-dose approach, with the consequence that "a reviewer would need to determine if the seven-day period should be viewed to begin with the first administration of the vaccine, the final administration of the vaccine, or some other option." FDA Br. at 8–9 (quoting Burk Decl. ¶ 20).

ICAN calls this argument "truly dumbfounding," stating that its request is "crystal clear" because the seven-day period follows "*the administration of the vaccine*." ICAN Br. at 18. If the period of review was longer than seven days, it says, then the trial is responsive; if not, then the trial is not responsive to ICAN's request. *Id.* But this response elides the question, which is when to start counting that seven-day period for a multi-dose vaccine. Indeed, ICAN's repeated use of a definite article to describe the starting point of the safety review period—i.e., following

the administration of *the* vaccine—overlooks that there is not just one administration and not just one dose of the vaccine. And because "safety review period" is not a term of art with an authoritative definition to which FDA employees or the Court can refer, the ambiguity remains.

This ambiguity is not a mere technicality. The parties' divergent interpretations of records produced in response to a separate request by ICAN for a different childhood Hepatitis B vaccine, Recombivax HB, demonstrate the point. *See* Burk Suppl. Decl. ¶¶ 8–16 (describing the background of this production). In their reply briefs, the FDA and ICAN disagree over how to interpret two Recombivax HB trials that the FDA produced. *See* Burk Suppl. Decl., Exs. 1–2; ICAN Reply Br., Exs. D–E. Like Engerix-B, Recombivax HB was tested by administering multiple doses, either two or three, spaced several months apart. Burk Suppl. Decl. ¶¶ 20–24. In the trials, patients were given a dose of the vaccine at zero, one, and six months of age. Patients were asked to "record any local or systemic complaints" they had "for 5 days following each injection of the vaccine." ICAN Reply Br., Ex. D at 3; *see also* Ex. E at 7. ICAN states that it is "dumbfounding" that the FDA could not conclude that these trials had five-day safety review periods and would therefore be unresponsive to its current request. ICAN Reply Br. at 4. But, as the FDA explains, the trial imposed such five-day monitoring periods after *each administration* of the vaccine. FDA Reply Br. at 4. In other words, the safety review period for the dose given at zero months would have lasted a minimum of six months because those same patients would have reported any complaints when they received their third and final dose. *See* Burk Suppl. Decl. ¶ 21; *accord* ICAN Reply Br. at 3 (clarifying that "'following administration' clearly means after reaching *each dose* of the vaccine" (emphasis added)).

These example trials reveal another latent ambiguity in ICAN's request, which is what it means to *review* for safety. The Recombivax HB trials asked the patients' parents to "record the

child's temperature for 5 days after each injection and note any local or systemic complaints," which ICAN understands to be five-day safety review periods. *E.g.*, ICAN Reply Br., Ex. D at 688. Yet as one illustrative trial explains, it was "initiated" on February 2, 1984 and was still "in progress" on December 31, 1985. *Id.* at 659. And the end of the report states that, "[t]o date . . . no serious or alarming reactions attributable to [the] vaccine have been reported." *Id.* at 693. Apparently, ICAN's definition of "safety review period" includes only day-to-day monitoring of the patient's temperature and complaints. But the FDA, for its part, "could not readily determine whether this trial would be responsive" to ICAN's request because the trial reports the absence of adverse reactions over a period much longer than seven days. Burk Suppl. Decl. ¶¶ 21–23.

This ambiguity is also evident in a trial for a different vaccine that ICAN provided as an example of how simple it is to determine a vaccine trial's safety review period. The trial required patients to record their temperatures and any reactions during the five days following an injection. ICAN Reply Br., Ex. C at 30. Patients were further required to report any "[s]erious adverse experiences in the 14 days following the vaccination." *Id.* ICAN refers to this example, but conspicuously does not say whether this procedure constitutes a five-day or fourteen-day safety review period. ICAN Reply Br. at 3. As a final demonstration, ICAN cites another clinical trial for a different vaccine in which "[e]ach child" in the trial was "followed clinically for 42 days following vaccination." ICAN Reply Br., Ex. A at 3. But the report, for which ICAN does not provide any results, also states that the trial was still "in progress" and includes the instruction that "[a]ny serious or alarming reaction, including death due to any cause during this investigation, whether related or not related to the test material, must be reported immediately to" the researchers overseeing the study, along with their contact information. *Id.* at 11–12. Again, ICAN interprets this report to mean that safety was reviewed only for 42 days

without considering (or providing) any information on effects that could have been reported outside the 42-day window, as the trial instructed patients to do. ICAN Reply Br. at 3.

In sum, the Court concludes that ICAN's request did not reasonably describe the records sought in such a way that an FDA employee could determine which trials were responsive to ICAN's request and which were not. That conclusion is further supported by the Court's finding that the sworn declarations submitted by the FDA, which explain its process and these issues in detail, are properly "accorded a presumption of good faith." *Carney*, 19 F.3d at 812.

Moreover, to the extent it is even possible based on the language of ICAN's request, the "sort of sifting and analysis" required to identify trials responsive to ICAN's request "is not a burden that the FOIA imposes on federal agencies." *Nat'l Sec. Couns. v. Cent. Intel. Agency*, 960 F. Supp. 2d 101, 158 (D.D.C. 2013). The purpose of FOIA is for the agency to produce documents, not to develop new opinions or "answer questions disguised as a FOIA request." *Hall*, 83 F. Supp. 3d at 102 (quoting *Hudgins v. I.R.S.*, 620 F. Supp. 19, 21 (D.D.C. 1985), *aff'd*, 808 F.2d 137 (D.C. Cir. 1987)). In other words, FOIA was "not intended to permit the public to commandeer agency employees as research assistants." *Nat'l Sec. Couns.*, 960 F. Supp. 2d at 160 n.28.

Nevertheless, even if the FDA receives an ambiguous FOIA request, it has an obligation to notify the requester of the ambiguity and then to make "[e]very reasonable effort . . . to assist" the requester in identifying the records sought. 21 C.F.R. § 20.40(b). The Court concludes that the FDA did just that. First, the FDA informed ICAN that its request did not reasonably describe the records, quoting the particular phrase at issue—"a safety review period longer than 7 days." Burk Decl., Ex. B-1. ICAN's response listed the elements of its request but did not provide any additional detail as to what it meant by the phrase. Burk Decl., Ex. B-2. Second, the FDA

offered to ensure that ICAN received all trials that it might consider responsive by producing the full 3,000 pages of clinical trial reports. Burk Decl., Ex. B-3 at 2. That way, the FDA explains, ICAN "would then have been free to sort and analyze the responsive records as it saw fit, including to make its own assessment regarding which 'clinical trial reports' had a 'safety review period longer than seven days.'" Burk Decl. ¶ 26. ICAN refused that broader production. Burk Decl., Ex. B-4. This series of exchanges satisfied the FDA's obligations under FOIA and its own regulations.

ICAN responds that it was "not interested in a document dump or in waiting for what will likely be an extended period of time for this broad production." ICAN Br. at 2; *see also id.* at 20 (characterizing the FDA's offer as "a large unwanted and unnecessary production dump"). But this response assumes that the FDA could have accurately satisfied ICAN's "narrower" request as ICAN interprets it. ICAN Reply Br. at 8. As explained, that is a faulty assumption. Additionally, while agencies should generally respond only to the request as worded, an agency may in select circumstances satisfy its FOIA obligations by responding to an overly "specific" request by conducting "a broader search" and production of documents. *Pinson v. U.S. Dep't of Just.*, 80 F. Supp. 3d 211, 216 (D.D.C. 2015). The Court finds that this is one such circumstance. And while this may have resulted in ICAN receiving a larger volume of documents than it would prefer, the Court does not find that the maximum possible production of approximately 3,000 pages is likely to overwhelm ICAN's ability to review them. *Accord* ICAN Br. at 21 (explaining that ICAN "can easily determine the safety review period in the clinical trials for these vaccines within minutes").

IV. Conclusion

For the reasons above, the Court GRANTS the FDA's motion for summary judgment and DENIES ICAN's motion for summary judgment. This resolves docket numbers 14 and 17.

The Clerk of Court is respectfully directed to enter judgment and close the case.

SO ORDERED.

Dated: March 28, 2022
New York, New York

ALISON J. NATHAN
United States District Judge